FLASTER/GREENBERG P.C.
By: Jeffrey A. Cohen, Esquire (JC7673)
1810 Chapel Avenue West
Cherry Hill, NJ 08002
(856) 661-1900 - Phone
(856) 661-1919 - Facsimile
jeff.cohen@flastergreenberg.com

Douglas H. Carsten (pro hac vice pending)
Foley & Lardner LLP
11250 El Camino Real, Suite 200
San Diego, CA 92130
Ph. (858) 847-6700
Fax. (858) 792-6773

Liane M. Peterson (pro hac vice pending)
Foley & Lardner LLP
3000 K Street, N.W. Suite 500
Washington, D.C. 20007
Ph. (202) 672-5300
Fax. (202) 672-5399

Attorneys for Defendant Pharmaceutical Associates, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SEPRACOR INC. and UNIVERSITY OF MASSACHUSETTS, Plaintiffs, v. PHARMACEUTICAL ASSOCIATES, INC., Defendant.	Case No. 08-cv-04718-MLC-TJB

DEFENDANT PHARMACEUTICAL ASSOCIATES, INC.'S ANSWER AND COUNTERCLAIMS TO PLAINTIFFS SEPRACOR, INC.'S AND UNIVERSITY OF MASSACHUSETTS' COMPLAINT

Defendant Pharmaceutical Associates, Inc. ("PAI"), hereby answers the Complaint filed by Plaintiffs Sepracor Inc. and University of Massachusetts (collectively "Plaintiffs") as follows:

Nature of the Action

1. PAI admits only that the Complaint purports to state an action for infringement of U.S. Patent No. 7,214,683 ("the '683 patent") and U.S. Patent No. 7,214,684 ("the '684 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*. PAI admits only that it submitted an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") for approval to commercially market Desloratadine Oral Solution 0.5 mg/mL before expiration of the '683 and '684 patents. PAI lacks sufficient information to form a belief as to the truth of the allegation that the '683 and '684 patents are owned by Sepracor Inc. and University of Massachusetts, and therefore denies the same. PAI denies the remaining allegations in paragraph 1 of the Complaint.

The Parties

2. PAI is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2 of the Complaint and therefore denies the same.

3. PAI is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 3 of the Complaint and therefore denies the same.

4. PAI admits only that it is a South Carolina corporation, having a place of business at 201 Delaware Street, Greenville, South Carolina 29605. PAI admits only that it manufactures pharmaceutical products, which are ultimately marketed and sold through wholesalers and/or distributors. PAI denies the remainder of the allegations set forth in paragraph 4 of the Complaint. Nevertheless, PAI waives the defense as permitted under Rule 12 by virtue of PAI's Answer and Counterclaims to the Complaint.

5. PAI admits only that it formulates, manufactures and packages generic pharmaceutical products. PAI denies the remainder of the allegations set forth in paragraph 5 of the Complaint.

6. Admitted.

7. PAI admits only that it submitted ANDA No. 90-616 to the FDA for approval to engage in the commercial manufacture, use or sale of Desloratadine Oral Solution 0.5 mg/mL. PAI denies the remaining allegations in paragraph 7 of the Complaint.

Jurisdiction and Venue

8. Admitted.

9. PAI denies the allegations set forth in paragraph 9 of the Complaint. Nevertheless, PAI waives the defense as permitted under Rule 12 by virtue of PAI's Answer and Counterclaims to the Complaint.

10. PAI admits only that it manufactures pharmaceutical products, which are ultimately marketed and sold through wholesalers and/or distributors. PAI denies the remainder of the allegations set forth in paragraph 10 of the Complaint. Nevertheless, PAI waives the defense as permitted under Rule 12 by virtue of PAI's Answer and Counterclaims to the Complaint.

11. PAI denies the allegations set forth in paragraph 11 of the Complaint. Nevertheless, PAI waives the defense as permitted under Rule 12 by virtue of PAI's Answer and Counterclaims to the Complaint.

The Patents In Suit and the Clarinex® Drug Product

12. PAI admits only that the '683 patent is entitled "Compositions of Descarboethoxyloratadine." PAI admits only that the '683 patent indicates on its face that it was

issued on May 8, 2007. PAI denies that the '683 patent was properly issued and that it is valid. PAI admits only that Exhibit A to the Complaint appears to be a copy of the '683 patent, but lacks sufficient information to verify its authenticity. PAI lacks sufficient information to form a belief as to the truth of the remaining allegations contained in paragraph 12 of the Complaint, and therefore denies each and every remaining allegation in paragraph 12 on that basis.

13. PAI admits only that the '684 patent is entitled "Methods for the Treatment of Allergic Rhinitis." PAI admits only that the '684 patent indicates on its face that it was issued on May 8, 2007. PAI denies that the '684 patent was properly issued and that it is valid. PAI admits only that Exhibit B to the Complaint appears to be a copy of the '684 patent, but lacks sufficient information to verify its authenticity. PAI lacks sufficient information to form a belief as to the truth of the remaining allegations contained in paragraph 13 of the Complaint and therefore, denies each and every remaining allegation in paragraph 13 on that basis.

14. PAI admits only that, according to the electronic records of the FDA, the '683 and '684 patents are identified in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" in association with Clarinex® oral syrup containing 0.5 mg/mL desloratadine. PAI denies the remaining allegations in paragraph 14 of the Complaint.

Acts Giving Rise to this Action

15. PAI admits only that it sent Plaintiffs a letter ("Notification Letter") notifying Plaintiffs that it had submitted ANDA 90-616 pursuant to section 505(j) of the Federal Food, Drug and Cosmetic Act in order to obtain approval to engage in the commercial manufacture, use or sale of Desloratadine Oral Solution 0.5 mg/mL. PAI lacks sufficient information to form a belief as to the truth of the remaining allegations contained in paragraph 15 of the Complaint, and therefore denies each and every remaining allegation in paragraph 15 on that basis.

16. PAI admits only that it submitted ANDA 90-616 to the FDA for approval to engage in the commercial manufacture, use or sale of Desloratadine Oral Solution 0.5 mg/mL. PAI denies the remaining allegations in paragraph 16 of the Complaint.

17. PAI admits only that the Notification Letter states that ANDA 90-616 includes a paragraph IV certification and that in PAI's opinion and to the best of its knowledge, the '683 and '684 patents are invalid. PAI denies the remaining allegations in paragraph 17 of the Complaint.

18. Denied.

19. PAI admits only that ANDA 90-616 indicates that PAI's proposed Desloratadine Oral Solution 0.5 mg/mL is bioequivalent to the reference listed drug Clarinex® Syrup (desloratadine) 0.5 mg/mL. PAI admits only that ANDA 90-616 and/or the proposed labeling indicate that PAI's proposed Desloratadine Oral Solution 0.5 mg/mL has the same active ingredient and the same route of administration and strength as the reference listed drug. PAI denies each and every remaining allegation in paragraph 19 of the Complaint.

Count I – Alleged Infringement of the '683 Patent by PAI

20. PAI incorporates its responses to paragraphs 1-19 of the Complaint as though fully set forth herein.

21. Denied.

22. Denied.

23. PAI admits only that ANDA 90-616 contains a paragraph IV certification with respect to the '683 patent. PAI denies each and every remaining allegation in paragraph 23 of the Complaint.

24. Denied.

Count II – Alleged Infringement of the '684 Patent by PAI

25. PAI incorporates its responses to paragraphs 1-24 of the Complaint as though fully set forth herein.

26. Denied.

27. Denied.

28. PAI admits only that ANDA 90-616 contains a paragraph IV certification with respect to the '684 patent. PAI denies each and every remaining allegation in paragraph 28 of the Complaint.

29. Denied.

Response to Prayer for Relief

PAI denies that Plaintiffs are entitled to the judgment and relief prayed for in paragraphs A through M of the Complaint.

AFFIRMATIVE DEFENSES

PAI alleges and asserts the following affirmative defenses in response to the allegations in the Complaint.

First Affirmative Defense

30. The manufacture, use, offer for sale, sale or importation of the product described in PAI's ANDA 90-616 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '683 patent and/or the '684 patent.

Second Affirmative Defense

31. The claims of the '683 patent and/or the '684 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112 and/or for double patenting.

Third Affirmative Defense

32. The Complaint fails to state a claim upon which relief can be granted.

Fourth Affirmative Defense

33. The Complaint fails to state a claim for willful infringement.

Fifth Affirmative Defense

34. PAI reserves all affirmative defenses under Fed. R. Civ. P. 8(c), the Patent Laws of the United States, and any other defenses that may now exist or in the future be available based on discovery.

COUNTERCLAIMS

Pursuant to Fed. R. Civ. P. 13, PAI hereby asserts the following counterclaims.

Counterclaim One (Declaratory Judgment Regarding the '683 Patent)

1. PAI realleges and reincorporates by reference the allegations contained in paragraphs 1-34.

2. The Court has jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338(a).

3. In light of Plaintiffs' baseless allegations that PAI has in the past and will in the future infringe, either directly or indirectly, the '683 patent, there is a real and immediate controversy concerning the '683 patent. This Court, therefore, has jurisdiction over this dispute under 28 U.S.C. § 2201.

4. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

5. PAI has not infringed and will not infringe, either directly or indirectly, any valid or enforceable claim of the '683 patent.

6. The '683 patent's claims are invalid for failure to comply with one or more of the following statutory provisions: 35 U.S.C. §§ 101, 102, 103, or 112.

Counterclaim Two (Declaratory Judgment Regarding the '684 Patent)

7. PAI realleges and reincorporates by reference the allegations contained in paragraphs 1-34.

8. The Court has jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. In light of Plaintiffs' baseless allegations that PAI has in the past and will in the future infringe, either directly or indirectly, the '684 patent, there is a real and immediate controversy concerning the '684 patent. This Court, therefore, has jurisdiction over this dispute under 28 U.S.C. § 2201.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

11. PAI has not infringed and will not infringe, either directly or indirectly, any valid or enforceable claim of the '684 patent.

12. The '684 patent's claims are invalid for failure to comply with one or more of the following statutory provisions: 35 U.S.C. §§ 101, 102, 103, or 112.

WHEREFORE PAI demands judgment dismissing Plaintiffs' Complaint with prejudice, finding this case exceptional under 35 U.S.C. § 285 and awarding PAI its reasonable attorneys' fees and costs of suit, and awarding PAI any further and additional relief as the Court may deem just and proper.

RESPECTFULLY SUBMITTED,

Dated: November 26, 2008

/s/ Jeffrey A. Cohen

Jeffrey A. Cohen, Esquire (JC7673)
FLASTER/GREENBERG P.C.
Commerce Center
1810 Chapel Avenue West
Cherry Hill, NJ 08002
(856) 661-1900
(856) 661-1919 (fax)
jeffrey.cohen@flastergreenberg.com

Douglas H. Carsten (pro hac vice pending)
FOLEY & LARDNER LLP
11250 El Camino Real, Suite 200
San Diego, CA 92130
Ph. (858) 847-6700
Fax. (858) 792-6773

Liane M. Peterson (pro hac vice pending)
FOLEY & LARDNER LLP
3000 K Street, N.W.
Suite 500
Washington, D.C. 20007
(202) 672-5300
(202) 672-5399

Attorneys for Defendant Pharmaceutical Associates, Inc.

Jury Demand

PAI requests a jury trial on all issues so triable.

/s/ Jeffrey A. Cohen
Jeffrey A. Cohen, Esquire (JC7673)
FLASTER/GREENBERG P.C.
Commerce Center
1810 Chapel Avenue West
Cherry Hill, NJ 08002
(856) 661-1900
(856) 661-1919 (fax)
jeffrey.cohen@flastergreenberg.com

Douglas H. Carsten (pro hac vice pending)
FOLEY & LARDNER LLP
11250 El Camino Real, Suite 200
San Diego, CA 92130
Ph. (858) 847-6700
Fax. (858) 792-6773

Liane M. Peterson (pro hac vice pending)
FOLEY & LARDNER LLP
3000 K Street, N.W.
Suite 500
Washington, D.C. 20007
(202) 672-5300
(202) 672-5399

Attorneys for Defendant Pharmaceutical Associates, Inc.

Dated: November 26, 2008

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that the matter in controversy is related to several other matters involving Plaintiffs herein and other defendants concerning the same patents, which have been consolidated into *Sepracor Inc., et al. v. Sun Pharmaceutical Industries, Inc., et al.*, 07-4213 (MLC)(TJB). In addition, the matter in controversy is related to several other matters consolidated into *In re Desloratadine Patent Litigation* MDL 1851, 07-3930 (MLC)(TJB), because all of the products at issue in the current matter and the previously identified matter are associated with Clarinex® products.

/s/ Jeffrey A. Cohen
Jeffrey A. Cohen, Esquire

Dated: November 26, 2008